CHAPTER 3
SECTION 1.6D

SMALL INTESTINE (SI); COMBINED SMALL-INTESTINE-LIVER (SI/L); AND MULTIVISCERAL TRANSPLANTATION

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I. PROCEDURE CODES

44200 - Small Intestine (SI) Transplant
47155 - Combined Small Intestine and Liver (SI/L) Transplant
44250 - Multivisceral Transplant

II. POLICY

A. Preauthorized benefits are allowed for SI, SI/L and multivisceral transplantation.

1. A TRICARE Prime enrollee must have a referral from his/her Primary Care Manager (PCM) and an authorization from the Health Care Finder (HCF) before obtaining transplant-related services. If network providers furnish transplant-related services without prior PCM referral and HCF authorization, penalties will be administered according to TRICARE network provider agreements. If Prime enrollees receive transplant-related services from non-network civilian providers without the required PCM referral and HCF authorization, Managed Care Support (MCS) contractors shall reimburse charges for the services on a Point of Service basis. Special cost-sharing requirements apply to Point of Service claims. For specific information on Point of Service cost-shares and catastrophic cap calculations, see Chapter 12, Section 12.2, Section 10.1 and Chapter 13, Section 14.1.

2. For Standard and Extra patients residing in a Managed Care Support (MCS) region, preauthorization authority is the responsibility of the MCS Medical Director, Health Care Finder or other designated utilization staff.

B. The designated preauthorizing authority shall only use the criteria contained in this policy when preauthorizing SI, SI/L and multivisceral transplantation.

C. Affirmative Patient Selection Criteria for SI Transplantation. Benefits may be allowed for medically necessary services and supplies related to SI transplantation when the transplantation is performed at a TRICARE approved transplantation center for pediatric patients under the age of 16 who:

1. Are suffering from irreversible intestinal failure, either functional or anatomic, requiring long term parenteral nutrition.

2. Have tried or considered all other medically appropriate medical and surgical therapies that might have been expected to yield both short and long-term survival comparable to that of transplantation.

3. Have a parent or legal guardian who have a realistic understanding of the range of clinical outcomes that may be encountered; and

4. Plans for long-term adherence to a disciplined medical regimen are feasible and realistic.

D. Affirmative Patient Selection Criteria for Combined SI/L Transplantation. Benefits may be allowed for medically necessary services and supplies related to combined SI/L transplantation when the transplantation is performed at a TRICARE approved transplantation center for patients who:

1. Have presence of end-stage parenteral nutrition induced liver disease; and

2. Meet the above patient selection criteria for SI transplantation and the patient selection criteria for liver transplantation as outlined in Chapter 3, Section 8.5, paragraph II.G. under Policy.

E. Affirmative Patient Selection Criteria for Multivisceral Transplantation. TRICARE may cost-share medically necessary services and supplies related to multivisceral transplantation when the transplantation is performed at a TRICARE approved transplantation center for patients who:

1. Have short bowel syndrome and have evidence of severe liver dysfunction and/or have other gastrointestinal problems such as pancreatic failure, thromboses of the celiac axis and the superior mesenteric artery or pseudo-obstruction affecting the entire gastrointestinal tract.

2. Have tried or considered all other medically appropriate medical and surgical therapies that might have been expected to yield both short and long-term survival comparable to that of transplantation.

3. Have a parent or legal guardian who have a realistic understanding of the range of clinical outcomes that may be encountered; and

4. Plans for long-term adherence to a disciplined medical regimen are feasible and realistic.

F. Donor selection criteria:

1. For SI transplantation, Cytomegalovirus (CMV) seropositive negative donors shall be used.

2. For combined SI/L transplantation, CMV seropositive donors will be allowed secondary to CMV seropositive negative donors if there is a shortage of organs available.

G. For a properly preauthorized patient, benefits may be allowed for medically necessary services and supplies related to SI, combined SI/L and multivisceral transplantation for:

1. Evaluation of a potential candidate's suitability for SI, combined SI/L or multivisceral transplantation whether or not the patient is ultimately accepted as a candidate for transplantation.

2. Pre- and post-transplantation inpatient hospital and outpatient services.

3. Surgical services and related pre- and postoperative services of the transplantation team.

4. The donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and the donated organ to the location of the transplantation center.

5. The maintenance of the viability of the donor organ after all existing legal requirements for excision of the donor organ have been met.

6. Blood and blood products.

7. FDA approved immunosuppression drugs to include off-label uses when determined to be medically necessary and generally accepted practice within the general medical community (i.e., proven).

8. Complications of the transplantation procedure, including inpatient care, management of infection and rejection episodes.

9. Periodic evaluation and assessment of the successfully transplanted patient.

H. Benefits may be allowed for Hepatitis B and pneumococcal vaccines for patients undergoing transplantation.

I. Benefits may be allowed for DNA-HLA tissue typing in determining histocompatibility.

III. POLICY CONSIDERATIONS

A. For beneficiaries who reside in TRICARE regions, preauthorization and retrospective authorization of SI, combined SI/L or multivisceral transplantation must meet the following two requirements:

1. Patient meets (or as of the date of transplantation, would have met) patient selection criteria; and

2. Transplantation facility is (or as of the date of transplantation, would have been) TRICARE approved for SI and/or combined SI/L transplantation at the time of transplantation.

B. For beneficiaries who fail to obtain preauthorization for SI, combined SI/L or multivisceral transplantation, TRICARE benefits may be extended if the services or supplies otherwise would qualify for benefits but for the failure to obtain preauthorization. If preauthorization is not received, the appropriate preauthorizing authority as outlined in paragraph II.A., under Policy, is responsible for reviewing the claims to determine whether the beneficiary's condition meets the clinical criteria for the SI, combined SI/L or multivisceral transplantation benefit. Charges for transplant and transplant-related services provided to TRICARE Prime enrollees who failed to obtain PCM referral and HCF authorization will be reimbursed only under Point of Service rules.

C. Benefits will only be allowed for transplants performed at a TRICARE approved SI or combined SI/L transplantation center. The contractor is the certifying authority for transplant centers within its region. Refer to Chapter 11, Section 11.5 for organ transplant certification center requirements.

D. Claims for services and supplies related to the transplantation will be reimbursed based on billed charges until such time as a DRG is established.

E. Claims for transportation of the donor organ and transplantation team shall be adjudicated on the basis of billed charges, but not to exceed the transport service's published schedule of charges, and cost-shared on an inpatient basis. Scheduled or chartered transportation may be cost-shared.

F. Benefits will be allowed for donor costs. Refer to Chapter 3, Section 1.6L for guidelines regarding donor costs associated with organ transplantations.

G. Charges made by the donor hospital will be cost-shared on an inpatient basis and must be fully itemized and billed by the transplantation center in the name of the TRICARE patient.

H. Acquisition and donor costs are not considered to be components of the services covered under the DRG and will be reimbursed based on billed charges. These costs must be billed separately on a standard UB-92 claim form in the name of the TRICARE patient.

I. Transportation of the patient by air ambulance may be cost-shared when determined to be medically necessary. Reference Chapter 7, Section 2.1.

J. When a properly preauthorized transplantation candidate is discharged less than 24 hours after admission because of extenuating circumstances, such as the available organ is found not suitable or other circumstances which prohibit the transplantation from being timely performed, all otherwise authorized services associated with the admission shall be cost-shared on an inpatient basis, since the expectation at admission was that the patient would remain more than 24 hours.

K. A referral and authorization is still required for TRICARE Prime enrollees who have other health insurance.

IV. EXCLUSIONS

A. SI transplantation is excluded when any of the following contraindications exist:

1. Significant cardiopulmonary insufficiency.

2. History or presence of aggressive and/or incurable malignancy.

3. Persistent abdominal or systemic infection.

4. Severe autoimmune disease.

5. Severe immunodeficiency disease.

6. Significant alcohol and/or drug abuse.

B. Combined SI/L transplantation is excluded when:

1. Any of the above contraindications for SI transplantation exist; and/or

2. Any of the contraindications for liver transplantation as outlined in Chapter 3, Section 8.5, paragraph II.A. under Exclusions exist.

C. Also excluded are:

1. Expenses waived by the transplantation center (e.g., beneficiary/sponsor not financially liable).

2. Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant or research program; unproven procedure).

3. Administration of an unproven immunosuppressant drug that is not FDA approved or has not received TRICARE approval as an appropriate "off-label" drug indication. Refer to Chapter 7, Section 7.3 for Policy requirements for immunosuppression therapy.

4. Pre- or post-transplantation nonmedical expenses (e.g., out-of-hospital living expenses, to include hotel, meals, privately owned vehicle for the beneficiary or family members).

5. Transportation of an organ donor.

V. EFFECTIVE DATE

A. January 1, 1996, for small intestine and combined small intestine-liver transplants.

B. February 1, 1998, for multivisceral transplants.

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